

unpatentable over Lenaghan. Applicants acknowledge, with appreciation, the helpful teleconference extended by Examiner Polluta on 01/04/99 to discuss the Proposed Amendment, which was faxed on 12/24/98. The Examiner has indicated that a new search would be conducted.

By this Amendment, Claim 1 has been amended. Reconsideration and allowance of amended independent Claim 1 is respectfully requested. Claim 1 has been amended to describe the inventive features with greater clarity and particularity and to more clearly distinguish over the prior art. Specifically, Claim 1 has been amended to specify the fact that the automatic identification system of the present invention is for use with a reading device and that the machine-readable information is located on a plurality of physically unconnected sponges. Furthermore, Claim 1 has been amended to emphasize that each sponge has its own differentiating machine-readable information locatable thereon which will not repeat on any other sponge used in a given surgical procedure. The claim has also been amended to emphasize that the resulting physically unconnected surgical sponges can be recognized and accounted for during a surgical procedure without reliance on human visual detection and counting ability to identify, differentiate and account for the surgical sponges.

No new matter is deemed to have been added by way of this Amendment. Antecedent basis for these limitations can be found, for example, on Page 6, Lines 11-13 and by review of Figure 1.

It is respectfully urged that the Lenaghan reference neither discloses nor suggests present applicants' invention. Lenaghan teaches the utilization of interconnected surgical sponges. (This is explicit in the Lenaghan reference, from its title to every section of content.) It is precisely the desirability to obviate such a requirement to which the present invention is directed. Claim 1 has been amended to emphasize the fact that present applicants' identification system is used on unconnected sponges.

The distinction between present applicants' system and Lenaghan's is also emphasized by the fact that present applicants' system utilizes machine-readable information. Lenaghan, on the other hand, necessitates that the indicia placed on the sponges is human-readable. As noted in Lenaghan, Column 3, Lines 38-47: "... the indicator tab includes an indicia 5 to identify the location of the particular sponge in the string. The number will notify the surgeon when he is approaching the end of the string, permitting the surgeon to call for another package of surgical sponges. Similarly, the indicator tabs may be colored either to identify the location of the surgical sponge or to differentiate between different packages of sponges. An identification number may also be printed directly upon the surgical sponge."

Lenaghan goes on to state, *"The identification tab may also be utilized in conjunction with a counter system, wherein a counter is disposed with the sponge to make certain that each of the sponges has been removed from the incision."*

There is nothing to suggest that the counter system involves the reading of machine-readable information. Lenaghan, instead, is focused on human-readability. As noted in Lenaghan, Column 5, Lines 19-22, the *"... connector may be brightly colored, such as blue or green, signifying the presence of a surgical sponge."*

The present invention has clear advantages over the Lenaghan system. No "interconnector" (i.e. linear connector 22), is required. Furthermore, there is no requirement or desirability for the sponges to be "serialized" (see Lenaghan, Column 4, Line 26). Indeed, present applicants' invention addresses and solves the long felt heretofore unresolved need for assuring that all surgical sponges are removed from the patient's body after the procedure.

Present applicants' invention is a faster, more reliable system to solve the problem of surgical sponge accountability. Their system saves time, money and increases the standard of health, as applicants note below:

"Our system can indicate to a surgical team if a sponge is missing or not, in a faster and more reliable way by the replacement of human visual identification and counting ability with automated machine recognition and determination in which the data present on each sponge which differentiates it from the next is readable to machine despite the presence of blood and other body fluids. It does not compromise the function of the sponge and functions without affecting the health of the patient. No other system has been able to do this."

Faster – the sponges can be identified and accounted for faster with an automatic identification system described herein as opposed to relying on human visual detection and counting ability. Sponges can be scanned in and scanned out of an automatically generated inventory with much greater speed than two personnel who count them by hand, which is the standard now. Furthermore, only one person will be required for our system, as opposed to two, which are required under the current system of sponge counting."

More Reliable – As each sponge has it's own differentiating data which will not repeat on any other sponge used in a procedure, the scanning device will only input each sponge into the system once, whereby sponges will not be double counted with our system as they may be when counted by hand and relying on human visual detection and counting ability. Double counting of sponges is often the reason for a sponge miscount and thus retained surgical sponges."

The present system saves money by:

- 1. Reducing time needed to count sponges (entire surgical teams are held up for prolonged lengths of time to count and recount sponges using human visual detection and counting ability);*
- 2. Reducing personnel needed from two to one; and,*
- 3. Reducing the number of product liability cases."*

Present applicants emphasize that the present invention can reduce the exposure time of hospital personnel to bloodborne pathogens from soiled surgical sponges not being properly disposed of immediately. Applicants note the following:

"Exposure and handling of soiled surgical sponges needs to be kept to an absolute minimum as they are the source of contamination: the faster they are properly disposed of, the less risk of exposure to bloodborne pathogens. In 1992, the Occupational Safety and Health Administration announced new regulations regarding bloodborne pathogens in US hospitals in which over five million healthcare workers in the US who could be reasonably anticipated to come into contact with blood and other body fluids would be subject to. The regulations are meant to reduce hospital personnel exposure to hepatitis B, HIV and other pathogens and requires hospitals to minimize employee exposure. This includes new devices for the counting of soiled surgical sponges. The physically interconnected surgical sponges of the Lenaghan patent would delay the proper disposal of soiled surgical sponges until all interconnected sponges in the string have been used. Hospital personnel would have to wait until every sponge in the interconnected string was finished being used before being properly disposed of. The problem here is that sponges used in a surgical procedure can be used for different amounts of time for different uses, for example, a sponge may be used momentarily for soaking up some extra blood around a delicate part of the wound and then be done with, or may be used for the duration of the procedure to be folded up and prop up an internal organ or body part and not be done with until the operation is over. Our system reduces risk of exposure to bloodborne pathogens by increasing the ability to quickly dispose of individual soiled surgical sponges as soon as they are done being used and therefore reduce exposure risk to hospital personnel."

Present applicants note that their invention does not require any "interconnector" to get in the way of the surgeon during an operation, both inside the wound and trailing out of the wound. The applicants note the following:

"Surgical procedures are very delicate, with a patient's health hanging in the balance. An interconnector which physically connects sponges together can get in the way of a delicate surgical procedure, threatening the health of the patient. Surgeons do not want a string in the way

of what they are doing, either inside the wound or trailing out of the opening, if they can avoid it by any means. Lenaghan's sponges provide that they are interconnected and the interconnector also trails out of the wound. Our system avoids this."

Present applicants go on to state:

"Our sponges are scanable, i.e. machine-readable, despite the presence of blood and other body fluids for use within our automatic accountability system. Furthermore, our system does so in a manner which does not inhibit the function of the sponges, won't hurt the patient (hence the reason we claim inert materials) and will not do so with prohibitive equipment (either too much or inappropriate to have in a surgical suite). Up to now, those skilled in the art thought, or were skeptical, that the technique used in the invention was unworkable or presented an insuperable barrier. Heretofore, a machine could not recognize data when it was covered with blood – not until our system was developed. Reading could not take place without compromising the function of the sponge."

In view of the foregoing, Claim 1 is deemed to be neither anticipated by nor rendered obvious by Lenaghan. Furthermore, Claim 1 is believed to have been amended to resolve any 35 USC 112 deficiencies. It is therefore deemed to be in allowable condition.

Present applicants note that Claim 17 can be amended in a similar manner as Claim 1, if after reviewing this Amendment, and the new search conducted, the Examiner believes that Claim 1 is allowable. Applicants also note that the above quotations can be proffered in the form of a declaration by the applicants if deemed desirable by the Examiner.


If the Examiner has any further questions, or believes that a telephone interview would be helpful to the advancement of the prosecution of the subject application, a telephone call to the undersigned would be appreciated.

Respectfully submitted,



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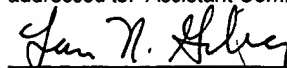
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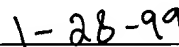
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Date